Full Title of the Study:

Emergency Medical Services **S**treaming **E**nabled **E**valuation **I**n **T**rauma: The SEE-IT Trial.

Short Trial Title:

The SEE-IT Trial

PROTOCOL V0.6 Date: 25/08/2022

This protocol has regard for the HRA guidance

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SHORT STUDY TITLE:	The SEE-IT Trial
Funders Reference	NIHR 130811
IRAS number	302216
TRIAL REGISTRY NUMBER AND DATE **ISRCTN Number / Clinical trials.gov Number:**	ISRCTN11449333 (22.03.2022)
SPONSOR and Reference	University of Surrey, Research Integrity and Governance Office (RIGO) SPON 2021 22 FHMS

KEY TRIAL CONTACTS

Chief Investigator	Professor Cath Taylor cath.taylor@surrey.ac.uk 01483 688862
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Funder	NIHR HS&DR Project Manager: Alan Marshall alan.marshall@nihr.ac.uk
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ii. TRIAL SUMMARY

Trial Title	Emergency Medical Services **S**treaming **E**nabled **E**valuation **I**n **T**rauma: The SEE-IT Trial	
Internal ref. no. (or short title)	The SEE-IT Trial (RN0480)	
Trial Design	(i) Feasibility RCT with a nested process evaluation. The study also has two observational sub-studies: (ii) in inner-city Emergency Operations Centre (EOC) who routinely use GoodSAM to assess acceptability and feasibility of use of GoodSAM in a diverse inner-city population (iii) in an EOC that does not currently use GoodSAM to act as a comparator site regarding the psychological wellbeing of EOC staff using vs not using GoodSAM.	
Trial Participants	a) Trauma casualties b) 999 callers (lay public) from (i) trial site; (ii) observational sub-study c) Emergency Operations Centre Staff from i) trial site; ii) observational sub-study site; iii) third EOC for comparator re: mental health	
Planned Sample Size	Targets based on convenience sampling over defined trial observation weeks a) 250 b) (i) 250: (ii) 100 c) (i) 86; (ii) 30; (iii) 86	
Follow up duration	The clinical records for trauma casualties will be followed up for 12 weeks post incident.	
Planned Trial Period	Study duration 18 months (1st October 2021 – 31st July 2023); Trial period for 6 months from 1st June 2022 to 30th November 2022.	
		Research Questions
Objectives	**To obtain data required to inform the design of a subsequent RCT**	• Event Rate: How many calls meet proposed inclusion criteria? • Screening Rate: How easily are eligible calls identified? • Outcomes: What is the effect size/precision for primary outcome(s) being considered for a subsequent trial? Can appropriateness of response be reliably measured? • Health economics: Can data regarding resource implications be reliably collected?

	To test trial processes including randomisation and data collection methods	• Randomisation: Is it feasible to randomise by workforce shift? Is it feasible to randomise by individual call? What is the potential for contamination? • Data collection: Can we collect decision-data real time and obtain accurate follow-up decision data retrospectively? What is the response rate to a follow-up 999 caller survey?
	To conduct a nested process evaluation to test the acceptability, feasibility and risk of psychological harm of using GoodSAM from provider and public perspectives	• Staff training: is brief software training (≤60mins) feasible to deliver and sufficient? • Video feasibility: What proportion of eligible calls are made using smartphones? Will/can the public follow the instructions? Is video useful in informing emergency dispatch? How is video from multiple calls about the same incident used to inform decision-making? How does the total call length compare between intervention and control arms? • Video acceptability: Is using video acceptable to 999 callers? Is using video acceptable to dispatch control room staff? • Psychological harm: Is there any evidence that live streaming is associated with risk of psychological harm for (a) 999 callers, and (b) staff who view the streamed footage?

LAY SUMMARY

A ‘trauma incident’ is when someone suffers injuries that may cause death or leave them with a long-term disability. Trauma incidents are the biggest killer of people aged under 45 in the UK: most often road traffic accidents. Following a trauma incident, most people will be taken to a hospital emergency department by an ambulance that has responded to a 999 call. Ambulances usually attend an incident by road, but in serious cases, an air ambulance (helicopter) or critical care paramedic (CCP) may be sent. The aim is to get the patient to the best hospital for treating their injuries without delay to improve their chances of survival, recovering from their injuries and not having long term problems.

When a 999 call is made, the person in the ambulance service who answers (the call taker) asks the caller to describe what they can see and how serious the injuries appear. This is so the dispatcher can decide how urgently, and what type, of help is required (e.g. whether a helicopter is needed). The caller may give incomplete or wrong information so sometimes too few or too many ambulances are sent. This can delay getting the right help to patients or mean that ambulances are not available for

others who need them. It is also costly for the NHS if ambulances or helicopters are sent when not needed.

We want to test a system called GoodSAM that allows the dispatcher to send a link in a text message to the smartphone of 999 callers. When the caller clicks on the link it uses the camera in their phone to send live images to the dispatcher (without recording it). This lets the dispatcher see what is happening at the scene, rather than just being told by the caller. This might help the dispatcher make quicker and more accurate decisions about which and how many ambulances to send, so that patients get the best help in the fastest possible time.

In this study, we will ask one ambulance dispatch centre to test GoodSAM for six weeks spread out over six months (to cover different periods when trauma incidents are higher/lower), so we can check how well it works in practice. We will count the number of calls when video might help the dispatcher decide what ambulances to send. We will check that the link works, and the dispatcher can see the images. After an incident is over, our researchers will look at the reports and assess if the right number and type of ambulances were sent to the scene. We will do this for incidents when GoodSAM was used, and when it was not (control group). This will help us to understand if film footage helped dispatchers send the right ambulances.

We will learn if members of the public are willing to allow their camera to be used and if dispatchers find it useful. An important part of this initial study will be to find out whether using live streaming upset the members of the public or dispatchers in any way. We will do this through interviews and a survey with members of the public and staff who did and did not use GoodSAM. Sources of support will be provided. We will also explore these issues in a second ambulance service located in a city so we can see if GoodSAM works in a similar way in an area where callers may not speak English for example.

This study will help us plan a larger study that will explore more fully the possible benefits of using film footage at trauma incidents. A panel of lay people will be set up to work with the research team throughout the project to make sure the views of patients and the public are fully represented.

SCIENTIFIC SUMMARY

Background: Major trauma is a leading cause of serious morbidity and mortality. Prompt, pre-hospital medical treatment following a traumatic incident can prevent death and improve patient outcome, thus timely and effective dispatch of appropriate emergency medical resources is critical. Dispatch prioritisation currently relies mostly on verbal phone information from incidents. It is estimated that up to half of air, and a quarter of road ambulance deployments, are inappropriate and use of live video has been recommended to improve appropriateness of triage and dispatch, but we lack evidence to support its use. GoodSAM is a freely available software that supports rapid streaming of live footage (that is not recorded) to dispatchers using callers' smartphone cameras, without the need for a pre-loaded app.

Research Question: Is it feasible to conduct a future RCT to assess the clinical and cost effectiveness of using GoodSAM live video streaming to improve targeting of emergency medical resources?

Aims and objectives: The overall aim of this research is to assess the feasibility of implementing and evaluating GoodSAM in a definitive RCT.

The objectives are:

1. To obtain data required to inform the design of a subsequent RCT (*i.e. event rate, screening rate, effect size/precision for outcomes, health economic data*)
2. To test trial processes including randomisation and data collection methods
3. To conduct a nested process evaluation to test the acceptability and feasibility of using GoodSAM from provider and public perspectives (*e.g. training, video feasibility, video acceptability, psychological harm to callers and/or dispatch staff*).

Design/Setting: Feasibility RCT with nested process evaluation in one Emergency Operations Centre (EOC) in SE England to determine if and how the clinical and cost effectiveness of using GoodSAM can be evaluated in a future definitive RCT. An observational sub-study is also included to assess acceptability of GoodSAM in an inner city EOC that may reach a more diverse population.

Methods:

Inclusion: All 999 calls involving major trauma operationalised as being a call judged by Helicopter Emergency Medical Services (HEMS) dispatcher and/or Critical Care Paramedic (CCP) as likely to require enhanced dispatch (either Critical Care Paramedic and/or HEMS dispatch) for Trauma.

Exclusion: All emergencies of a suspected medical origin. All trauma calls where: (i) caller not at the scene; (ii) call from a landline; (iii) call from another emergency service: police or fire; (iv) calls where resource (excluding community first responder) will arrive on scene before live streaming could be activated; (v) call ended before transfer for activation of live streaming; (vi) calls where another incident takes priority; and (vii) calls where clinical acuity is found to be lower than threshold for entry to the study (not major trauma).

Randomisation: 999 calls during six observation weeks (42 days; 84 shifts), allocated 1:1 by working shift to intervention or standard care using a computer-generated randomisation list.

Control: Standard care ambulance dispatch protocol with a 999 caller using a telephone (voice only) and the dispatcher using the NHS Pathways ambulance dispatch tool.

Intervention: GoodSAM live streaming (*not recording*) from 999 callers via link sent by SMS text. Calls allocated to intervention will initially follow the standard NHS Pathways dispatch protocol until the ambulance dispatch prioritisation has been determined by the call handler. An ambulance will be dispatched as normal, without delay. GoodSAM video streaming will then take place and ambulance resource allocation may be adjusted following this (NB: road ambulance can only be escalated NOT de-escalated; Critical Care Paramedic (CCP) or Air Ambulance can be escalated or de-escalated).

Primary outcome: Decision regarding the feasibility of undertaking a definitive RCT based primarily on meeting progression criteria stated below.

Secondary outcomes: Speed of appropriate emergency services dispatch (using time-stamped data from start of 999 calls to appropriate deployment; appropriateness based on expert consensus criteria and using data up to 3 months post-incident), stand-down rate (de-escalation), missed jobs (e.g. not prioritised for HEMS/CCP despatch, either due to lack of resource or inappropriate prioritisation), requests for further ambulance resources from scene. Psychological harm will be assessed pre and post intervention period in staff viewing the footage (and also measured in staff within a comparison EOC not using GoodSAM); and in callers from both arms 6-8 weeks post-incident, using two validated scales.

Sample size: Conservative event rate = 250 trauma incidents over the 6 observation weeks (125 allocated to intervention) which will allow estimate of true event rate within precision of +/-0.75 events/day; and allow estimation of speed of appropriate response with a standard error of <5%.

A health economic analysis will be undertaken from NHS and societal perspectives to inform the design of a full economic evaluation within the future trial. The process evaluation will include analysis of streaming usage data; observation of Emergency Operations Centre processes (e.g. fidelity to study protocol); and interviews with staff and 999 callers. A sub-study in an inner-city EOC will examine acceptability of GoodSAM in a population with greater diversity.

Analysis: estimates and confidence intervals of key rates (e.g. number of eligible calls/day) to inform subsequent RCT. Qualitative data will be analysed thematically using Framework Method.

Progression criteria:

- ≥70% (Green); ≥50% (Amber), <50% (Red) of callers with smartphones agreeing and able to activate live streaming;
- ≥ 50% (Green); ≥30% (Amber), <30% (Red) of requests to activate result in footage being obtained (allowing for margin for lack of 3G/4G/5G coverage).
- Air ambulance stand-down rate reducing by ≥ 10% (Green) ≥5% (Amber) and/or change in dispatch decision confirmed as appropriate in ≥ 10% cases (Green) ≥5% (Amber). No change in stand down rate and/or change in dispatch decision (Red)
- No evidence of increased psychological harm to intervention arm 999 callers (vs control); or evidence of increased harm to EOC staff (pre vs. post intervention) compared to staff in a comparison EOC not using GoodSAM/streamed from scene footage (Green/Amber); Evidence of significantly greater harm in either 999 callers or staff (Red).
- In addition to the quantitative progression criteria described above, the research team will take into account qualitative data collected as part of this study (e.g. interviews, observations, and free text questions in surveys) when reviewing progression to a subsequent definitive trial. This is particularly important with regards to the acceptability and experience of using live streaming during trauma incidents.

iii. FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this trial)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
National Institute for Health Research (NIHR) Health Services and Delivery Research (HS&DR) Programme	£459,981.23
GoodSAM https://www.goodsamapp.org/ Via Mark Wilson	Free access to GoodSAM for duration of trial

iv. ROLE OF TRIAL SPONSOR AND FUNDER

This study/project is funded by the National Institute for Health Research (NIHR) Health Services and Delivery Research programme (NIHR HS&DR 130811). The funder has no role in the design, conduct, analysis, interpretation, manuscript writing or dissemination of findings.

The trial sponsor takes overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. They are legally responsible for governance/oversight of the conduct of the trial and study as a whole but has no role in the design, analysis, interpretation, manuscript writing or dissemination of findings.

v. ROLES AND RESPONSIBILITIES OF PROJECT STEERING GROUP, PROJECT ADVISORY GROUP AND PPIE

Steering Group

The project steering group will monitor progress against milestones and spend against budget, provide advice where necessary (for example around dissemination and impact), promote the project, and facilitate communication between organisations with stakeholders and help maximise dissemination and impact of findings. Membership will be independently appointed and NIHR-approved (two meetings will be held over the course of the study). Prof. Gavin Perkins (Professor in Critical Care Medicine, University of Warwick) will be invited to chair this steering group. The steering group will include experts in pre-hospital care, trauma medicine and ambulance dispatching, as well as relevant methodological expertise.

Project Advisory Group

The project will also be supported by a Project Advisory Group (PAG) that will be chaired by Janet Holah (PPI Lead) who will also chair a separate but inter-connected PPIE Group. The PAG will meet 4 times over the course of the study to coincide with key timepoints in the project and provide a forum for input and support regarding the data collection, analysis, and production of outputs and dissemination. The membership will include members of the expert panel formed to develop the criteria for rating appropriateness, together with other relevant clinical and methodological expertise, and will be attended by core members of the research team.

The PPIE group will also be chaired by Janet Holah and will include 5 lay representatives who will meet with the PPIE lead quarterly to coincide with PAG meetings and enable flow of input and contributions into and out of the PAG.

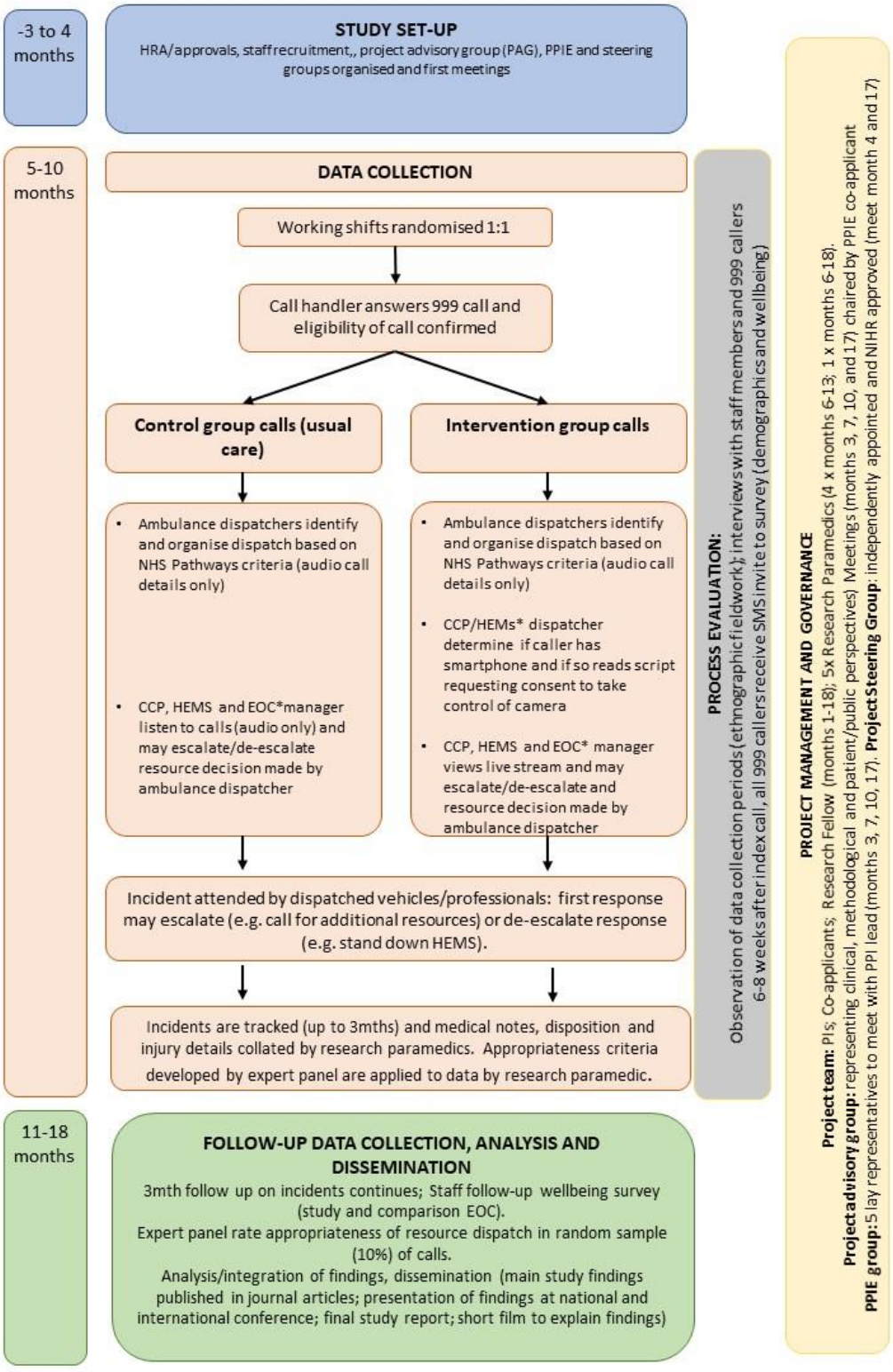
Each oversight group will agree to appropriate terms of reference approved by the Chair.

vi. INVESTIGATORS

NAME	Position
Professor Cath Taylor	Co-CI: Professor of healthcare workforce organisation and wellbeing
Professor Richard Lyon	Co-CI: Professor of pre-hospital emergency care
Professor Jill Maben	Co-I: Professor of health services research and nursing
Professor Simon Skene	Co-I: Professor of Medical Statistics and Director of Surrey Clinical Trials Unit. Lead for trial and statistics
Professor Heather Gage	Co-I: Professor of Health Economics and Director of Surrey Health Economics Centre. Lead for health economics
Dr Carin Magnusson	Co-I: Lecturer in Health Services Research. Co-lead for process evaluation (with Cath Taylor)
Professor Mark Cropley	Co-I: Professor of Health Psychology.
Professor Julia Williams	Co-I: Professor of Paramedic Science; Head of Research at South East Coast Ambulance NHS Trust (SECAmb): the main feasibility RCT site. Lead for trial at SECAmb; line manage research paramedics.
Ms Janet Holah	Co-I: PPI Lead
Mr Craig Mortimer	PI at SECAmb
Mrs Kate Bennett-Eastley	Trial Statistician (Surrey CTU)
Dr Jeewaka Mendis	Senior Medical Statistician (CTU)
Matthew Glover	Research Fellow in Health Economics
Research Paramedics (TBA x 5)	SECAmb Research Paramedics

Research Paramedic (TBA) x 1	Research Paramedic for LAS sub-study (employed by SECAmb)
Dr Lucie Ollis	Research Fellow: Lead for Process Evaluation and Project Manager (study co-ordinator)
Study Administrator (TBA)	Administrative support for study
Jason Morris	PI at London Ambulance Service
Theresa Foster	PI at East of England Ambulance Service
Robert Crouch	Local PI at University Hospital Southampton NHS Foundation Trust
Harriet Tucker	Local PI at St George's University Hospitals NHS Foundation Trust
Adebayo Da-Costa	Local PI at Medway NHS Foundation Trust
Christine Dixon	Local PI at Surrey and Sussex Healthcare NHS Trust
John Clulow	Local PI at Maidstone and Tunbridge Wells NHS Trust
Janet Sinclair	Local PI at East Sussex Healthcare NHS Trust
Jonathon Leung	Local PI at East Kent Hospitals University NHS Foundation Trust
Zen Gashi	Local PI at Dartford and Gravesham NHS Trust
Matthew Edwards	Local PI at King's College University Hospital NHS Trust
Louisa Zouita	Local PI at Royal Surrey County Hospital NHS Foundation Trust
Chetan Trivedy	Local PI at University Hospitals Sussex NHS Foundation Trust

STUDY FLOWCHART (NIHR 130881 Taylor/Lyon)
Emergency Medical Services Streaming Enabled Evaluation In Trauma: The SEE-IT Trial



*CCP/HEMS/EOC: Critical Care Paramedic/Helicopter Emergency Medical Service/Emergency Operations Centre. These are the emergency service professionals that can escalate/de-escalate dispatch in standard practice and will be the staff that see the live streaming in the intervention arm.

1 BACKGROUND AND RATIONALE FOR THE STUDY

Major trauma (MT) is any injury with potential to cause prolonged disability and death and is a leading cause of serious morbidity and mortality. Advanced emergency medical care at the scene of an accident, before the patient arrives at hospital can prevent death and improve patient outcomes. To save lives and prevent disability, timely and effective dispatch of appropriate emergency medical resources are critical [1]. Air ambulances (helicopters) and Critical Care Paramedics are often deployed to trauma incidents where severe injury is suspected.

Two dispatching systems are in current use in the UK: The Medical Priority Dispatch System (MPDS) and the NHS Pathways systems. On taking a 999 call, the dispatcher's role is to obtain and act upon information about the scene and the clinical state of the casualties. This is often referred to as 'situational awareness': "*being able to perceive critical cues about the external domain, the systems and the tasks, then to comprehend and project a future state of the situation, are important to making appropriate decisions*" [2]. However, lay public 999 callers may not be able to provide accurate information due to language barriers, subjectivity and the emotional impact of being present at the scene [3]. Dispatch response is recognised as the weakest link in the emergency medical response chain [4], often involving either under-triage (insufficient quantity or capability of resources dispatched), or over-triage (unnecessary and costly deployment or advanced medical services that are not required) [5-8].

Currently, UK emergency services' call centres mainly rely on verbal phone information from incidents to prioritise dispatch. Studies show that up to 50% of air ambulance deployments, and 25% of land ambulance dispatches to suspected trauma cases are inappropriate [5-8], highlighting the limitations of decisions based on audio information only. This has major clinical and health economic implications.

NHS policies actively encourage the use of innovative technologies to improve patient and health system outcomes [9]. Using video to improve triage and dispatch decisions is a key recommendation in a recent policy review of emergency response in the London Ambulance Service [10]. The benefits of using video in other healthcare settings is growing, e.g. for remote healthcare consultation [11-12] but evidence is sparse in relation to use in emergency response. GoodSAM [13] uses callers' smartphone cameras to stream live footage directly to the dispatchers, offering unique opportunities to improve precision in dispatch. This is particularly important for major trauma where specialist critical care resources, such as air ambulances, are often needed. It is in current use in some ambulance services [14-16] but its impact on clinical or economic outcomes has not yet been evaluated.

2 AIMS AND OBJECTIVES

Aim: To conduct a feasibility RCT with nested process evaluation to inform the design of a definitive RCT to evaluate the clinical and cost effectiveness of using GoodSAM to improve targeting of emergency response resources.

Objectives and Research Questions:

Objective 1: To obtain data required to inform the design of a subsequent RCT

- Event Rate: How many calls meet the proposed inclusion criteria?
- Screening Rate: How easily are eligible calls identified?
- Outcomes: What is the effect size/precision for primary outcome(s) being considered for a subsequent trial? Can appropriateness of response be reliably measured?
- Health economics: Can data regarding resource implications be reliably collected?

Objective 2: To test trial processes including randomisation and data collection methods

- Randomisation: Is it feasible to randomise by workforce shift? Is it feasible to randomise by individual call? What is the potential for contamination?
- Data collection: Can we collect decision-data real time and obtain accurate follow-up decision data retrospectively? What is the response rate to a follow-up 999 caller survey?

Objective 3: To conduct a nested process evaluation to test the acceptability, feasibility and risk of psychological harm of using GoodSAM from provider and public perspectives

- Staff training: is brief software training (≤60mins) feasible to deliver and sufficient?
- Video feasibility: What proportion of eligible calls are made using smartphones? Will/can the public follow the instructions? Is video useful in informing emergency dispatch? How is video from multiple calls about the same incident used to inform decision-making? How does the total call length compare between intervention and control arms?
- Video acceptability: Is using video acceptable to 999 callers? Is using video acceptable to dispatch control room staff?
- Psychological harm: Is there any evidence that live streaming is associated with risk of psychological harm for (a) 999 callers, and (b) staff who view the streamed footage?

3 OUTCOME MEASURES/ENDPOINTS

3.1 PRIMARY AND SECONDARY OUTCOMES FOR FEASIBILITY TRIAL

Primary outcome: Decision regarding the feasibility of undertaking a definitive RCT based primarily on meeting pre-defined progression criteria (see page 24).

Secondary outcomes:

- Speed of appropriate emergency services dispatch (see below for definition of this)
- Stand-down rate (de-escalation)

- Missed jobs (e.g. not prioritised for HEMS/CCP despatch, either due to lack of resource or inappropriate prioritisation)
- Requests for further ambulance resources from scene.
- Psychological harm will be assessed pre and post intervention period in staff viewing the footage (and also measured in staff within a comparison EOC not using GoodSAM); and in callers from both arms 6-8 weeks post-incident, using two short validated scales: (1) The Impact of Event Scale-Revised [17] is a 22 item self-report measure that assesses subjective distress caused by traumatic events (e.g. intrusion, avoidance and hyperarousal); (2) The General Health Questionnaire-12 item version [18] screens for psychological distress based on the frequency of symptoms reported in common mental disorders such as depression and anxiety.

3.2 PROPOSED PRIMARY OUTCOME FOR SUBSEQUENT TRIAL (IF SUPPORTED BY FEASIBILITY)

As this is a feasibility trial, there is not a primary outcome measure. The proposed primary outcome for the subsequent trial is speed of appropriate emergency services dispatch. Speed is the time from start of 999 call to the arrival of each appropriate dispatch vehicle(s) using routinely collected time-stamp data.
Appropriateness will be determined based on the consensus criteria defined before the trial starts. The criteria for judging appropriateness of dispatch will be agreed by expert consensus. The expert panel (to include up to 6 panel members) will meet for a one-day consensus meeting. The expert panel will have extensive experience in dispatching ambulance resources to major trauma. A selection of experts will be invited to include some from outside the region, to provide independent input, including:

- Dr Fionna Moore (Medical Director, SECAmb)
- Dr Magnus Nelson (Associate Medical Director, SECAmb and HEMS Consultant, Air Ambulance Kent, Surrey Sussex)
- Mr Richard de Coverly (Assistant Director Operations, Air Ambulance Kent Surrey Sussex)
- Mr Stuart Elms (Chief Operating Officer, Lincs & Notts Air Ambulance)
- Mr Dan Cody (Critical Care Paramedic, SECAmb)
- Dr Duncan Bootland (Major Trauma Lead, Brighton & Sussex University Hospitals).

Appropriateness is defined as the need for intervention and/or transport by the response vehicle/staff that were called to scene (e.g. for HEMS dispatch that a critical care intervention and/or transportation by helicopter was required [8]). The criteria for each type of dispatch/staff members will be discussed using anonymised worked case examples. A binary outcome decision tree will be developed with the reasons for appropriate/inappropriate dispatch categorised and agreed (inappropriate dispatch will be further categorised as being ‘over’ or ‘under’ resourced).

4 TRIAL DESIGN

Feasibility RCT with a nested process evaluation

5 TRIAL SETTING

The study as a whole will involve three Emergency Operations Centres in total:

- SECAmb (South East Coast Ambulance Service NHS Foundation Trust) will participate in the RCT.
- LAS (London Ambulance Service) will be the setting for an embedded observational study of the acceptability of GoodSAM
- East of England Ambulance Service (not using GoodSAM currently) will be the setting for recruitment of staff for comparing rates of psychological harm.

6 PARTICIPANT ELIGIBILITY CRITERIA

This study includes three different types of participant and three different components of the overall study. The inclusion criteria for each are presented below.

6.1 Inclusion criteria

Study Participant	Main Feasibility Trial	Inner-city observational sub-study	Staff wellbeing sub-study
Trauma Casualties	All trauma casualties during the 6 trial observation weeks who are the subject of 999 calls involving major trauma, judged by HEMS dispatcher and/or CCP as likely to require enhanced dispatch.	All trauma casualties during observed shifts (up to 24 shifts over a 3-month period) that involve trauma and are screened by HEMS dispatchers or critical care advanced paramedic practitioner dispatchers (APPs) who attempt to use GoodSAM during the call.	Not applicable
Lay public 999 callers	999 callers (excluding those that dispatchers identify as a Child Caller under 16 years old) during the 6 trial weeks where the incident involves major trauma (defined as per above).	All 999 callers (excluding those that dispatchers identify as a Child Caller under 16 years old during observed shifts (up to 24 shifts over a 3-month period) that involve trauma and are screened by HEMS dispatchers or critical care advanced paramedic practitioner dispatchers (APPs) who attempt to use GoodSAM during the call.	Not applicable

EOC Staff	All Critical Care Paramedics, HEMS dispatchers, and research paramedics.	All HEMS dispatchers and critical care advanced paramedic practitioner dispatchers (APPs)	All Critical Care Paramedics and HEMS dispatchers.

6.2 Exclusion criteria

Study Participant	**Main Feasibility Trial**	**Inner-city observational sub-study**	**Staff wellbeing sub-study**
Trauma Casualties	All emergencies of a suspected medical origin (e.g. heart attack, stroke) All trauma calls where: (i) caller not at the scene; (ii) call from a landline; (iii) call from another emergency service: police or fire; (iv) calls where resource (excluding community first responder) will arrive on scene before live streaming could be activated; (v) call ended before transfer for activation of live streaming; (vi) calls where another incident takes priority; and (vii) calls where clinical acuity is found to be lower than threshold for entry to the study (not major trauma).	All emergencies of a suspected medical origin or that are not handled by HEMS dispatcher or critical care advanced paramedic practitioners dispatchers (APPs).	Not applicable
Lay public 999 callers	All 999 callers where the incident is suspected to be of medical origin (e.g. heart attack, stroke), or where the call meets an exclusion criteria as per above.	All 999 callers where the incident is suspected to be of medical origin or where the call is not handed by HEMS dispatcher or critical care advanced paramedic practitioner dispatchers (APPs).	Not applicable
EOC Staff	All other EOC staff	All other EOC staff	All other EOC staff
999 callers	All 999 callers under 16 years old	All 999 callers under 16 years old	Not applicable

7 TRIAL PROCEDURES

All 999 calls (both arms) will commence with the standard care protocol resulting in dispatch prioritisation by NHS Pathways and standard ambulance dispatch. Subsequently, 999 callers in the intervention arm will activate live streaming, if they have a smartphone and consent, and dispatch will be adjusted if required (see study flowchart). NB: Road ambulance can only be escalated NOT de-escalated; Critical Care Paramedic (CCP) or Air Ambulance resources can be escalated or de-escalated.

7.1 Recruitment: identification and consent

(a) Trauma Casualties:

Identification: Research Paramedics will be observing all shifts that are included in the main feasibility trial or observational study and will be able to determine eligibility of the call based on the criteria above. For any eligible calls in the main feasibility trial site, the CAD (Computer-Aided Dispatch) record number(s) relating to the call will be recorded by research paramedics and enable linkage to any casualties involved in that incident for further follow-up purposes. No further follow-up is required in the observational sub-study thereby no identifier will be recorded.

Consent to stream with GoodSAM: Consent to stream using GoodSAM will be sought from the patient (by the 999 caller, with support from the dispatcher) where they have capacity.

Patients who have sustained major trauma may be unconscious, or in a presenting condition which may prohibit them from providing informed consent for participation in the study at the time of the event. Therefore, routinely obtaining informed consent may not be possible, or indeed desirable as we do not want to interrupt and/or delay clinical care or cause further distress to the patient. Due to this, together with the fact that streamed footage will not be recorded nor seen by anyone other than health professionals, we will seek approval for streaming to occur without the need for informed consent from casualties and others on scene if this is not possible (via an application to the Confidentiality Advisory Group under Section 251), but that streaming would cease if there was any objection from anyone on scene.

Consent to access records (only applicable to trial site patients): Informed consent will be sought either from the casualty, their consultee or the casualty's parent or guardian, where applicable to access their data at a later date. Initially, consent would be sought from the patient once they are deemed out of critical risk (e.g. moved from intensive care ward/unit onto a standard hospital ward) or by approaching their consultee. Shortly after the incident the research paramedic will contact the lead designated research nurse at the hospital where the casualty has been transported to discuss when it would be appropriate to approach the casualty (or consultee/parent/guardian) and whether this will be undertaken by the study research paramedic or the research nurse on site (determined according to availability). As there is no urgency to gain access to data (access is not needed until approx. 3 months post-incident), there will be no need

for an urgent approach to a consultee. For casualties who have yet to regain capacity by approximately 2 months post-incident, the research nurse(s) at the hospital will make the initial approach to the relevant consultee. If the casualty regains capacity to consent before the data is extracted (approx. 3 months post-incident) they will be approached and invited to re-consent for themselves. If the casualty is under the age of 16, their parent or guardian will be approached for consent for their child to participate in the research. If the child is able to understand the research, is happy to take part and can write their name, they will be provided with study information sheets that are age-appropriate and asked to sign an assent form, if they want to. This approach will ensure that vital medical treatment is not delayed and is consistent with the Declaration of Helsinki and the Mental Capacity Act (2005) concerning requirements for informed consent in emergency situations. Approval has been sought via the CAG (Section 251 application) to access medical records for casualties who die before consent can be sought (and where there is not a power of attorney in place for that individual). If casualties have left the hospital before they could be approached in person, the research nurse team at the trauma unit/centre to which they were transported will contact them (or their next of kin if appropriate) by telephone to explain about the study and ask for permission to send them the study information sheet and consent form. This will be sent electronically (email) or by post as preferred by the patient/consultee. A follow-up telephone call will be offered after the information has been received and they have had time to read and consider their involvement, in order to answer any questions and determine whether or not they are willing to consent for participation in the study. Electronic consent will be acceptable. Verbal consent from patients/consultees via the telephone will also be accepted. The research nurse/consenter will read each step of the consent document to the patient/consultee and ask them to confirm verbally that they understand each step of the consent form and the researcher will initial to confirm the participant has understood and verbally agreed. The consent form will be signed and dated by the person taking consent and a copy sent to the patient/consultee (either by post or email as they prefer). Contact details will be provided should any information be deemed incorrect.

(b) Lay Public 999 callers

Identification: As per the trauma casualties above, Research Paramedics will be observing all shifts that are included in the main feasibility trial or observational study and will be able to determine eligibility of the call based on the inclusion criteria. No details about 999 callers are taken or retained other than their telephone number. In the trial site, the CAD number linked to the call will enable identification of the telephone numbers of eligible callers. In the observational sub-study, the research paramedic will alert HEMS dispatchers or critical care APPs if a call is eligible so that they can be approached as described below. Verbal consent will initially be taken during the 999 call by the HEMS dispatcher or critical care APPs for the research paramedic to contact them after the call has ended.

Consent to stream with GoodSAM: Due to the nature of the research it will not be possible to follow standard ethical procedures for 999 callers (e.g. providing information sheets for them to read with sufficient time to consider before signing consent forms) prior to using their smartphone for live streaming (in the intervention arm callers). This is very common with ambulance service research due to the time-critical nature of the emergencies. However, the critical care dispatcher (either critical care paramedic or HEMS dispatcher) who is speaking to the 999 caller will seek consent from the caller prior to pursuing video streaming consultation and the caller will have the right to refuse. A script is used for this purpose (see '*GoodSAM Incident Caller Instructions*' document).

Consent to participate in the survey/interview: In the main feasibility trial, within a week of their 999 call, each 999 caller in the control and intervention arm of the study will be sent a text invitation to participate in the study (via the Computer Aided Dispatch system used by the EOC), with a link to the Participant Information Sheet and consent form, and contact details for the research team. In the observational sub-study, 999 callers will be first approached about the study by the HEMs dispatcher or critical care APP at the end of their GoodSAM call. They will be asked for permission to store their name and number and share with the researcher so they can be invited to participate in the study. Those who consent to this will initially be contacted by phone so the researcher can explain the study and ask their permission to send them further details about the study via text message or email (999 callers' choice). With consent, the researcher will then send them a text message (or email) with a link that will take the caller to the PIS and consent form, which if they complete will take them directly to the survey about their experiences of calling 999. This has been added to protocol v0.5 due to input/suggestions from the SEE-IT PPIE group. The researcher will send a reminder invitation text/email up to one week after the incident to any 999 callers that have yet to respond to the survey.

(c) EOC Staff

Identification: The staff relevant to this project in each of the three EOCs involved will be identified by the local PI.

Consent to use GoodSAM and being observed as part of the study: In the trial study site, the use of GoodSAM for this study will be approved at organisational level and staff will be required to follow the organisational protocols if they are working on a shift where it should be used. In the observational sub-study GoodSAM is being used routinely and HEMS dispatchers and critical care APPs will be individually consented to being observed in the study.

Consent to participate in the survey/interviews: The local PI in each of the three sites will send an email to all eligible staff with the relevant Participant Information Sheet. Consent to participate in the survey including consent to be potentially invited to participate in an interview will be built into the survey form. Staff that complete the first survey will be asked to provide their email address

for the purpose of sending the follow-up survey, potentially inviting them to participate in an interview (if they consent to this) and entering them into the prize draw.

7.1.2 Payment

EOC staff will have their time paid for participating in interviews either in payment to the Trust for them to be paid overtime (Trial site) or in payment of a £45 voucher for their time (EOC inner city). They will also be entered into a prize draw for a £50 retail voucher upon receipt of both (pre and post) surveys. There will be 5 vouchers available to each site.

999 callers will be offered a £10 Love2Shop voucher or donation to Kent Surrey and Sussex Air Ambulance charity (trial site) London Air Ambulance (observational study site) upon receipt of their completed survey and again if they participate in an interview.

7.2 The randomisation scheme

Working shifts (e.g., day:0700-1900, or night:1900-0700), allocated 1:1 to intervention or standard care using a computer-generated randomisation list, prepared by the Trial Statistician at Surrey CTU in advance of the trial shifts.

The feasibility of randomising by individual call will be explored as the preferred methodology for the definitive RCT and will be tested across at least two shifts in the final observation week.

7.2.1 Method of implementing the randomisation/allocation sequence

Randomisation will be overseen by a Statistician at Surrey CTU who is independent of the Trial Team. A sampling frame for the randomisation will ensure balanced coverage of standard care vs. standard care + GoodSAM across days of the week/times of day and across the trial observation weeks to ensure appropriate balance between shifts.

Shifts will be allocated 1:1 to standard care vs standard care + GoodSAM using an appropriate statistical software and methods documented in a Randomisation Plan including method of delivery to sites, via password protected emails to be opened at the beginning of each shift.

The feasibility study will also examine the potential for the randomisation of individual incident calls to inform the design of a future large-scale RCT. This will be trialled at sites during the final observation weeks and detailed in an amendment to the randomisation plan. The precise method for delivery will be subject to discussion with sites to ensure implementation without disruption to the response service being provided.

7.3 Blinding

Due to the nature of the intervention, blinding of trial participants and research staff at sites is not possible. However, potential biases will be minimised by concealment of the randomisation allocation as

described above (until maximum of a week before each trial week) and ensuring that data collection from electronic records and analysis is undertaken without reference to intervention allocation wherever possible.

7.4 Baseline data

During observation periods within the trauma centres, incident calls and response will be logged, and the research paramedic will ensure sufficient detail is recorded for records and clinical notes for trauma casualties to be retrieved by the study team to inform decisions about appropriateness of dispatch. Data collection will be minimised to ensure no interference with usual practices.

Other useful baseline data will include detail about staffing on the shift. Comparison of incidents presented with historical data will be useful to assess representativeness of the chosen periods.

Prior to the study opening, the study team will ensure staff taking part are suitably trained in the study processes including implementation of the GoodSAM protocol.

7.5 Trial assessments

There are no assessments in relation to the trial except for psychological harm measures (see below). The timing and types of data to be collected are described here.

<u>Decision making data and clinical data from trauma casualties</u>
Decision-making during eligible calls will be recorded real-time by research paramedics in the control room, using a study-specific and piloted proforma. As well as recording the CAD number, they will also record: Details of the trauma event (single/multiple casualties; blunt/penetrating trauma; general nature e.g. fall from height/ road traffic accident/ assault etc); and the Age and Sex of casualties.

Subsequently the CAD number will be used by the research paramedic to extract time stamped data on dispatch decisions and to track the casualties involved in the incident in order to approach for consent. Following patient/next of kin consent, they will collate relevant data from patient records (e.g. patient disposition, confirmed injuries), using data available up to three months post incident and rate appropriateness using the agreed criteria against these data. A random 10% sample of incident information and dispatch decisions from intervention and control calls will be independently reviewed by the expert panel using the same data, to assess reliability. Speed to appropriate dispatch – the time from initiation of 999 call to dispatch of appropriate ambulance vehicle(s) will be collected from routinely collected time-stamp data.

<u>Psychological harm</u>

999 callers in the main trial site and EOC staff in the main trial site and the comparison EOC site will be invited to complete surveys to assess psychological harm. The measures will be sent using Qualtrics (electronic survey platform) for completion online, with a short accompanying demographic section to:
a) all clinicians that may use GoodSAM during the study duration: HEMS dispatchers (n=6), CCPs (n=60), Dispatch Managers (n=20), and the research paramedics (n=5) will be invited via email to complete the scales online in the pre-intervention period (months 1-4) and post-intervention (months 11-13). The survey will also be sent to CCPs, HEMS and Dispatch Managers in a comparison EOC that is not using GoodSAM to aid interpretation of this data;
b) all 999 callers (both arms) confirmed to be aged 16+ who consent to participate will be invited by SMS text 6-8 weeks after the index incident to complete the scales.

7.6 Long term follow-up assessments

The clinical notes for trauma casualties will be followed up for 3 months post incident to inform decisions about appropriateness of dispatch.

999-callers will be surveyed 6-8 weeks post-incident.

7.7 Embedded Process Evaluation

Aim: to inform understanding of how the intervention works (or not) to influence speed of appropriate dispatch and to assess the feasibility and acceptability of study processes in preparation for a larger trial through:

1. Analysis of usage data: for example this will include refusal and failure rates and reasons; and the length and quality of video received. ***(Objective 3: What proportion of eligible calls are made using smartphones? Will/can the public follow the instructions? Is video useful in informing emergency dispatch? How is video quality impacted by time of day/season/other factors?)***
2. Observation of EOC processes (3-6 hours for 3 days in each observation week i.e. 54- 108 hours across 18 days) covering fidelity to study protocol ***(Objective 2: What is the potential for contamination?)*** and impact of contextual variability (time of day, weather, number of incoming calls). ***(Objective 3: Is video useful in informing emergency dispatch? How is video from multiple calls about the same incident used to inform decision-making?)***.
3. Interviews with purposively sampled range of EOC staff, including some staff arriving at scene of traumatic incidents (n=12-18), and including some from the inner city EOC (10-12) to explore experiences of use of live streaming. Staff will be selected to include different types of staff, age, gender and experience ***(Objective 3: Is video useful in informing emergency dispatch? Is using video acceptable to dispatch control room staff? Is there any evidence that live streaming is associated with risk of psychological harm for staff who view the streamed footage?)***

4. Interviews with 999 callers regarding experiences and acceptability of use of GoodSAM. Between 15-20 people from each EOC (30-40 in total) will be purposively sampled from those volunteering for interview through survey completion. They will be selected to represent a range in demographics (age, ethnicity, gender), type of incident they witnessed and evidence or not of psychological harm from survey responses. ***(Objective 3: Is using video streaming acceptable to 999 callers? Is there any evidence that live streaming is associated with risk of psychological harm for 999 callers?)***

The observation and interviews will be conducted by an experienced researcher (Lucie Ollis: named Research Fellow). The observational and interview data collection – and analysis - will be underpinned by theories informing the proposed mechanisms of effect (Situational Awareness, SA [19] and Decision Making, DM [20], and the implementation of a new technology (TAM [21-23] and CFIR [24]). Events will be observed in real time and the use of GoodSAM will be understood in the context of how the use of visual technology impacts on staff assessment of situations and action taken (SA and DM), as well as the factors influencing how people relate to the introduction of a new technology (TAM). Equally, in situations where GoodSAM is not used, theories of SA and DC will inform observations in context. Unlike the Research paramedics in the trial EOC who will be observing purely to document the decision-making and changes to decision-making during eligible calls, Lucie Ollis will be documenting her observations regarding the decision making for eligible calls in terms of the information that is used to determine dispatch; and observing the intervention shifts for adherence to the protocol (e.g. script being read to 999 callers; ability to send the SMS texts and use of the video footage). Observational data will be recorded using fieldnotes capturing both descriptive and conceptual observations/interpretations. Data will be analysed concurrent to its collection where possible and will inform the topic guide for interviews (e.g. following up on observations about challenges or benefits of use of GoodSAM to gain views from the users' perspectives).

Quantitative data (e.g. usage data) will be analysed descriptively. Qualitative data (interviews, field notes) will be analysed for patterns in the data using a framework approach [25]. Interviews will be digitally recorded and transcribed verbatim. Key topics and themes emerging from interviews and fieldnotes will be identified through familiarisation with the transcripts/fieldnotes, and with reference to the objectives and the theory underpinning the study. A series of thematic charts will be produced with data from each transcript summarized under each theme. These charts will enable exploration of patterns and confirming as well as disconfirming data, allowing comparison within and between interviewees, and across themes. Data from all sources will be integrated to answer the overarching research questions using mixed methods matrices [26]. These are similar to the matrices used in framework analysis [25] and facilitate the comparison of findings from qualitative and quantitative sources. Data may complement, support/extend, conflict or be 'silent' in one dataset compared to the other. Reasons for any conflict or contradiction between qualitative and quantitative sources will be explored using the framework provided by Moffat et al [27] specifically by considering: (i) treating the methods as fundamentally different; ii) exploring the methodological rigour of each component; iii) exploring dataset comparability; iv) collecting further data and making further comparisons; v)

exploring the process of the intervention; and vi) exploring whether outcomes of the two components match.

7.8 Withdrawal criteria

It is not possible to gain fully informed consent for use of GoodSAM at the time of the 999 call/incident for reasons outlined earlier. However, if the 999 caller refuses consent to stream from their camera phone, or if there is any objection from the patient or anyone on scene, streaming would cease. In relation to withdrawing from the study:

(i) Trauma casualties: The retention of the basic information collected at the time of the call (estimated age, sex, and categorical data about the nature of the incident and injuries) will be collected without consent with approval from CAG under Section 251. In relation to their follow-up data, they would be able to withdraw their consent any time up to 12 weeks post-incident.

(ii) 999 Callers: survey and interview data can be withdrawn up to 2 weeks after completion (thereby prior to analysis).

(iii) EOC staff: survey and interview data can be withdrawn up to 2 weeks following completion.

8 TRIAL INTERVENTION

The intervention is the GoodSAM “live on-scene” video streaming function. This will be activated with 999 callers, via a link sent by the EOC to the 999 caller using SMS text. The footage is then live streamed to the EOC (without recording), enabling assessment of the scene and injuries.

Calls allocated to intervention will initially follow the standard NHS Pathways dispatch protocol until the ambulance dispatch prioritisation has been determined by the call handler. An ambulance will be dispatched as normal, without delay. GoodSAM video streaming will then take place and ambulance resource allocation may be adjusted following this (NB: road ambulance can only be escalated NOT de-escalated; Critical Care Paramedic (CCP) or Air Ambulance can be escalated or de-escalated).

9 STATISTICS AND DATA ANALYSIS

9.1 Sample size calculation and planned recruitment rate

As this is a feasibility RCT, the sample size is based on the expected event rate (number of trauma events observed) and the resulting precision on estimates of feasibility parameters, including the ability to inform the sample size of a definitive trial.

Event rate: A conservative estimate is six eligible calls per day based on HEMS data, which is more accurate than NHS Ambulance Service data, and HEMS will attend most major trauma incidents [28].

Thus, we would expect to observe 250 trauma incidents over the 6 observation weeks (125 allocated to intervention), which would allow estimate of true event rate within precision of +/- 0.75 events/day.

Appropriateness of dispatch: HEMS data suggest a 30% inappropriate deployment rate (either stood down en route; or where intervention and/or transport were not required) [28]. The expected event rate (above) will allow estimation of speed of appropriate response with a standard error of <5%.

9.2 Statistical analysis plan

A full Statistical Analysis Plan (SAP) will be written and agreed before the first substantive analysis of unblinded trial data, and approved by the steering committee [29].

As a feasibility study, statistical analysis will focus on providing estimates and confidence intervals of key rates such as the number of eligible calls per day, uptake of video intervention and timing and appropriateness of dispatch to inform a subsequent RCT. Outcome measures will be summarised by arm and estimates reported with confidence intervals to inform future sample size calculations. ***(Objective 1: estimating event rate, screening rate, effect size/precision for outcomes)***

Reporting will conform to the CONSORT guidelines and relevant extensions for feasibility and pilot trials [30].

Progression to a subsequent definitive trial will be based upon satisfying pre-defined progression criteria and a signal that use of GoodSAM may be associated with improved speed of appropriate dispatch. Criteria will be reviewed by our steering committee pre-trial but are likely to include:

GREEN; proceed to definitive study - **GO**	**AMBER**; consider protocol amendments to improve criteria	**RED**; do not proceed to main trial - **STOP**
• ≥70% of callers with smartphones agreeing and able to activate live streaming	• ≥50% of callers with smartphones agreeing and able to activate live streaming	• <50% of callers with smartphones agreeing and able to activate live streaming
• ≥50% of requests to activate live streaming resulting in footage being viewed	• ≥30% but <50% of requests to activate live streaming resulting in footage being viewed	• <30% of requests to activate live streaming resulting in footage being viewed
• Air Ambulance (HEMS) stand-down rate reducing by ≥10% and/or change in dispatch decision as a result of GoodSAM footage confirmed as being appropriate in ≥10% cases	• Air Ambulance stand-down rate reducing by ≥5% and/or change in dispatch	• No change in Air Ambulance stand-down rate and/or

	decision as a result of GoodSAM footage confirmed as being appropriate in ≥5% cases	change in dispatch decision as a result of GoodSAM footage
Rates of psychological harm (based on the survey measures cited above) not significantly greater in 999 callers using GoodSAM compared to those not; and no significant difference in change to psychological harm over time in staff (CCPs, HEMS dispatchers, Dispatch Managers) compared to change in staff in a comparison EOC not using GoodSAM/streamed from scene footage	---	Evidence of significantly greater harm in either 999 callers or dispatch managers using GoodSAM compared to EOC.

In addition to the quantitative progression criteria described above, the research team will take into account qualitative data collected as part of this study (e.g. interviews, observations) when reviewing progression to a subsequent definitive trial. This is particularly important with regards to the acceptability and experience of using live streaming during trauma incidents.

The SAP will outline any expected exploratory analysis of outcomes that may be useful to inform a subsequent RCT including any signal of potential efficacy, but it is noted that the study is not powered for this and so interpretation would be limited to the direction and magnitude of any effect. Missing data, including outcome data will be summarised, but all observed data will be included in any analysis according to the randomised allocation following the intention-to-treat principle.

Other feasibility parameters such as individual incident randomisation and data collection methodology will be similarly reported. ***(Objective 2: To test trial processes including randomisation and data collection methods)***

9.3 Economic evaluation (*Objective 1: can data regarding resource implications be reliably collected?)*

The primary purpose of the health economic analysis is to assess the feasibility of gathering data on the resource implications, costs and effects of the dispatch decisions under standard care and when adjusted for the GoodSAM video intervention. It will assess whether using video evidence from the scene of the accident reduces the proportion of dispatch decisions that are deemed inappropriate (using the decision trees determined by the expert panel), the impact of use of the video streaming on time to dispatch and the associated cost implications. The comprehensive analysis of GoodSAM is complex, involving judgements on appropriateness and quality of care, and potentially important indirect effects, such as motorway traffic delays due to inappropriate use of an air ambulance. Potential adverse health outcomes may arise if inappropriate or insufficient resources are dispatched.

The significance of these effects, and how to accommodate them in a full trial will be carefully considered.

The health economic analysis will consider the perspectives of the NHS and society. Data on personnel and services first dispatched (intervention and control arms), changes to initial response triggered by video streaming (intervention arm) and subsequent upgrades or downgrades at the scene of the incident will be analysed. Three levels of dispatch will be distinguished: road ambulance only, critical care paramedics (in a car); and air ambulance. The air ambulance team includes emergency care specialist doctors and more advanced equipment for treatment at the scene. It also enables faster transport of victims to trauma centres.

Analysis will be at the level of individual incidents and combined for group comparisons. Initial decisions may be inappropriate, either because too many resources are dispatched (incurring unnecessary costs) or because too few resources are dispatched (resulting in potential adverse health outcomes). The extent to which dispatch decisions deviate from appropriate (according to the decision trees proposed by the expert panel), will be costed on an incident-by-incident basis. The excess costs of over dispatch will be compared with the usual care and GoodSAM groups. The 'savings' associated with under dispatch will be estimated, considered in relation to potential adverse events, and compared between groups.

Dispatch data will be extracted from records by study researchers, including the time stamps that are routinely collected. Where possible, nationally validated sources will provide unit costs of services utilised [31]. Other costs will be sought from service providers, e.g. air ambulance services. Unit costs will be converted into an appropriate cost per unit of time to characterise the opportunity costs of dispatch decisions (likely cost per minute). Costs associated with the intervention will be computed, including training costs. Findings will be summarised in a cost-consequences framework to provide a preliminary indication of the balance of costs and effects, with granular cost implications of decisions made during the incident. Consideration will be given to potential ratio metrics that may be suitable for comparing the two arms and could inform further studies (e.g. cost per appropriate dispatch). Levels of missing data and the magnitude of external effects will be considered in the context of formulating recommendations for the conduct of the economic analysis in a future definitive trial presented.

10 DATA MANAGEMENT

10.1 Data collection tools and source document identification

Data will be collected by both research paramedics (trial data) and the Research Fellow (process evaluation). The research paramedics will use a study-specific and piloted proforma to collect decision-making data during eligible calls. All data will be entered into an Excel spreadsheet and saved on SECAmb secure server initially. Once anonymised (CAD number removed), data will be

transferred (using secure file transfer service 'DropOff') to the Chief Investigator (Cath Taylor) who will save the folder in the University of Surrey secure location (Trusted Research Environment). The CAD and Study ID linkage document will be stored on SECAmb secure server, only accessible to the Research Paramedics and local PIs (Julia Williams and Craig Mortimer).

Survey data (psychological harms, 999 callers and EOC staff) will be entered directly into Qualtrics by participants (University of Surrey account). Once the survey has 'closed' at each timepoint (approx. 4-8 weeks after the initial invitation to complete the survey), all data will be downloaded from Qualtrics into the secure university server location for analysis and deleted from Qualtrics.

Interviews will be audio recorded on an encrypted recorder and transferred within 48 hours onto the secure university server location. They will be transferred securely to the approved university transcriber for transcription. Once transcripts have been received and verified for accuracy, they will be anonymised and the audio recordings deleted. Transcriptions will be stored in the secure university server location.

A detailed Data Management Plan has been produced (see 'GoodSAM Data Management Plan') outlining the processes for completion, transfer and storage of study data in line with Trust and University policies, the requirements of the Sponsor and GDPR. Trauma incidents will be identified by incident number, and participants (999 callers, trauma casualties and EOC staff) will be given a unique study identifier to enable linkage of data/follow up but avoid identification of personal sensitive data.

Participant details will be held securely on Trust secure servers, and not recorded in the trial database. Trial data (once transferred) will be stored on secure servers at the University of Surrey, and any linked NHS data will be pseudo-anonymised prior to transfer. The data management plan will be shared with all those responsible for data collection on the trial and will form the basis of a DPIA and data processing agreements between the parties.

10.2 Access to Data

Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections- in line with participant consent.

10.3 Archiving

The end of the trial is defined as the date of final 'database lock', on resolution of final data queries. At the end of the trial, the Sponsor will archive securely all centrally held trial related documentation for 10 years. Arrangements for confidential destruction will then be made. It is the responsibility of Principal

Investigators to ensure data and all essential documents relating to the trial held at site are retained for 10 years in accordance with institutional policy as well as national legislation and for the maximum period of time permitted by the site.

Essential documents are those which enable both the conduct of the trial and the quality of the data produced to be evaluated and show whether the site complied with the principles of Good Clinical Practice (GCP) and all applicable regulatory requirements.

The Sponsor will notify sites when trial documentation held at sites may be archived. All archived documents must still continue to be available for inspection by appropriate authorities upon request.

11 MONITORING, AUDIT & INSPECTION

The research team within each study site shall be responsible for their own monitoring and ensuring the accuracy and quality of the data, data collection. The level and type of monitoring expected is not more than would be expected as part of standard procedures in research which sites should be performing as a matter of course to maintain oversight of the data and processes at their site. Examples of the types of information that sites would be expected to monitor are listed below. Please note sites may monitor additional information outside of this list should they feel it is necessary.

- The study is conducted appropriately and in accordance with the protocol and GCP
- All staff involved in the trial have the necessary qualifications for their delegated duties and have received the necessary training
- Only eligible participants are enrolled onto the study
- Informed consent is taken and documented accurately
- All data is entered accurately, completely and promptly
- Site files are maintained and kept up to date
- The Research Team is kept informed of any problems in a timely manner

12 ETHICAL AND REGULATORY CONSIDERATIONS

12.1 Research Ethics Committee (REC) review& reports

The study will not commence until approval has been received from the HRA (including REC and CAG approval), and local approvals are in place.

Substantial amendments that require REC review will not be implemented until the REC/CAG (and HRA) grants a favourable opinion, and the local R&D have agreed to implement the amendment.

All correspondence with the REC will be retained in the Investigator Site File/Trial Master File and annual and end of study reports will be written by the Chief Investigator and submitted as required.

12.2 Peer review

The study described within this protocol has received independent expert peer review through a two-stage review process with NIHR including review by their prioritisation and funding committees as well as external peer reviewers.

12.3 Public and Patient Involvement

Patient and Public Involvement and Engagement (PPIE) is essential to this project. Our proposal was initially presented at a South East Coast Ambulance Service NHS Foundation Trust (SECAmb) Patient and Public Engagement in Research event to gather views to inform the project team's decisions. This was well received and generated informative discussion which has influenced the development of the proposed research. Participants wanted to know about the safety and feasibility of live streaming in stressful, emergency situations and they wondered how palatable it would be to the general public to be asked to do this. Their feedback led to inclusion in this research of a survey and interviews with 999 callers (general public) about experiences and potential harm.

During the grant submission process, comments were invited from PPIE representatives on SECAmb's research governance group regarding the lay summary, benefits of the study, potential impact on patients and the importance of the research question. Feedback at this stage led to alterations to the outline application, including issues around recruitment, modification of dissemination plans and revision of the plain English summary. In addition we sought input from a wider audience in the general public regarding the acceptability of streaming video footage from trauma incidents by developing an electronic survey which was distributed via the Kent Surrey and Sussex Air Ambulance Service Facebook, Twitter and Linked In pages. In this survey we asked 2 questions based on the feedback we had from the outline stage of our grant submission, to gain views on acceptability of live streaming if they were in an accident; and to ask their views about whether they felt live streaming from a 999 call would increase psychological harm over and above witnessing the trauma without streaming (questions pasted below). In just a few days of the survey being opened, we received 547 responses. Of these, 535 (97.8%) respondents stated Yes to question 1: that it would be acceptable for the live streaming to happen (only n=9, 1.7% said no, and n=3, 0.6% said they were unsure); and 445 (81.3%) stated No: that they
did not feel streaming would significantly worsen psychological distress (n=62, 11.3% were unsure about this; and only 37, 6.8% said they thought it would worsen psychological distress). The learning that has occurred from working with services users, patients and the general public has been extremely beneficial to the development of this research and we all share the same vision, which is to ensure accurate, safe dispatch.

Our lay representative co-applicant, Janet Holah, has extensive experience of working with senior groups and team working within boards and she will chair the project advisory group (consisting of all

co-applicants and members of the research team, as well as other clinical and methodological advisers), meeting four times over the course of the study, and will also coordinate a separate PPIE panel with 5 members that will also meet four times over the course of the study to advise the research team. Janet will also liaise with other relevant PPIE groups such as the groups accessed through the KSS Air Ambulance Twitter and Facebook groups above and also through the South East Coast Ambulance Service NHS Foundation Trust's Inclusion Group and service users' fora.

In conjunction with Janet, Julia Williams (co-applicant), is very experienced working with lay, public and service users and they will facilitate a learning needs assessment with these groups to identify any learning and training needs. At this stage it is unknown what these specific needs might be, but, we as an example we could usefully offer two half day workshops looking at the following areas to ensure that our PPIE panel is well prepared to support the project:

- Introduction to ambulance service research in general
- Introduction to research in SECAmb and Kent, Surrey and Sussex Air Ambulance
- Familiarisation with: Research terminology; Medical terminology; Acronyms; Abbreviations
- Introduction to the research methods being used in the GoodSAM study
- The role of research ethics
- Contributing effectively in meetings
- Knowing when to share stories and personal views
- Managing emotions
- Introduction to reviewing documents

Also, there is an ambulance service version of Good Clinical Practice (GCP) just being approved by NIHR and we believe this would be an excellent vehicle to focus on during a second workshop to ensure that all the members are familiar with these elements of research governance. Members will be trained and reimbursed at INVOLVE rates.

As well as their input to all our strategic and management decisions during study implementation, we anticipate our PPIE group will be particularly involved at key stages. While planning data collection, we will need their input to develop all patient-facing materials such as participant information sheets, consent forms, and recruitment information for participants. We will involve our group members during analysis of data, sense- checking emerging results with them and considering how to interpret findings.
Finally, we will work with the PPIE group to determine the most effect ways of dissemination of the results of this study, using a variety of approaches from journal publishing and conference presentations, through to use of social media sites and the production of a short film reporting on findings and research processes.

12.4 Regulatory Compliance

The trial will not commence until favourable opinion from HRA (including REC and CAG approval), and appropriate approvals from participating sites are in place (e.g. confirmation of capacity and capability from the research sites, and green light from sponsor to commence).

If there are any amendments to the study, the Chief investigator or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

12.5 Protocol compliance

It is recognised that as a feasibility study with an embedded process evaluation, minor deviations from the protocol will be expected and will help inform the feasibility of undertaking a definitive study. However, the study teams and participating staff at Emergency Operations Centres will inform the Chief Investigator and/or Sponsor as soon as they are aware of a possible serious breach of compliance, so that the Sponsor can fulfil its regulatory and oversight requirements. For the purposes of this section a 'serious breach' is one that is likely to affect to a significant degree:

- The safety or physical or mental integrity of the subjects/participants in the study, or
- The scientific value of the study.
- Other deviations will be logged and dealt with appropriately. Any decisions relating to the inclusion or otherwise of such data in the analysis will be fully documented in accordance with the detailed statistical analysis plan.

12.6 Data protection and patient confidentiality

Trauma Casualties: data collected prior to consent will only consist of their estimated age (not date of birth) and sex, and categorical data regarding the nature of the incident. Each casualty will be allocated a unique Study ID. For trauma casualties within the feasibility trial site, their study ID number will be linked to the CAD number for the incident. The CAD number will not be stored in any datasets controlled by the University of Surrey and only held on Trust premises. The document linking CAD numbers to Study ID numbers will be kept on a secure password protected server on the NHS Trust network. Linkage is required in order to identify them to follow them up for consent purposes. No follow-up/further data will be required for the observational sub-study therefore no CAD number will be recorded in that study site and only the anonymised data (estimated age, sex and details of the incident/injuries) at the time of the incident.

999 Callers: No details about 999 callers are taken or retained by researchers without their consent. In the observational sub-study consent will be sought verbally for their name and number to be stored and shared with the research paramedic so they can be sent information about the study. In the main feasibility trial, the number will be used to send a text message (via the Computer Aided Dispatch system used in the EOC) including links to the consent form and participant information No further

data will be held on 999 callers unless they consent to complete the survey and thereby provide data. Each 999 caller will be allocated a unique study ID and this will be used in the database with their survey data and on transcripts for callers

interview data. Phone numbers will only be used for the purpose of inviting 999 callers to participate in the study and (upon receipt of consent) to compete the survey. If 999 callers complete the survey and are happy to be potentially contacted to participate in a follow-up interview, they will be asked to include their contact details (name and email or telephone number). This information will only be used for the purposes of contacting them to invite and arrange the interview and will be stored securely (on the password protected university server), separately from any data they provide, and destroyed immediately after interviews have taken place.

EOC staff: Will be contacted via their NHS email addresses (initial invitations will be by the local PI to each site and their details only shared if they consent to participate). All data (survey/interview) will be pseudonymised with a unique study ID.

12.7 Financial and other competing interests for the chief investigator, PIs at each site and committee members for the overall trial management

n/a no financial or other competing interests

12.8 Indemnity

The sponsor has in place relevant insurance for the design and the management of the study. The NHS indemnity scheme is in place to provide insurance for the conduct of the research on NHS premises. The sponsor has arrangements in place for payment of compensation in the event of harm to the research participants where no legal liability arises.

12.9 Access to the final trial dataset

Access to the final dataset will be restricted to members of the research team. The data will be kept securely and in a pseudo-anonymised format so as to protect personal sensitive data from being associated with any individual or participant.

Requests for data sharing will be considered by the Chief Investigator in consultation with the Sponsor as outlined in 10.3.

13 DISSEMINIATION POLICY

13.1 Dissemination policy

The main output will be knowledge regarding the feasibility and acceptability of GoodSAM in practice and learning about data collection and research processes to inform the development of a larger trial

of the clinical and cost effectiveness of GoodSAM. This study will also produce novel data regarding the psychological wellbeing of 999 trauma callers and of dispatchers, including any additional positive or negative impact of streaming on wellbeing.

Findings will be disseminated to all key stakeholders (local and national policy makers, commissioners, providers, emergency response staff, patients and public, academic audiences) by a wide variety of means, including:

- Publications in relevant journals, e.g. Emergency Medicine Journal; Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine; British Paramedic Journal.
- Presentation at national and international meetings and conferences, e.g. Emergency Medical Services conference, 999 Research Forum Conference, London Trauma conference, College of Paramedics conference, Ambulance Leadership Forum, Ambulance Association Chief Executives meeting.
- Summary report sent to all ambulance services in United Kingdom; and to the relevant professional bodies and the Director for Acute Care at NHS England.
- Media releases, facilitated by the University's press office, to reach the general public
- Project webpage hosted by University of Surrey and via social media (Twitter) to provide regular updates on progress.
- Production of a short film to share findings with public/non-specialist audience (disseminated via Patient and Public Involvement and Engagement (PPIE) groups through the CRN; and Annual Member meetings held in all UK ambulance services).
- Presentation of the findings via an international webinar hosted by the College of Paramedics as interest in this work extends beyond the UK.

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Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	3	28.02.2022	LO/CT	**Addition of 10 NHS organisations** (trauma units/centres) that may need to be included in the study for patient recruitment/data collection. This is not a change to the protocol. 1. University Hospital Southampton NHS Foundation Trust. Investigator name: Robert Crouch (robert.crouch@uhs.nhs.uk) 2. St George's University Hospitals NHS Foundation Trust. Investigator name: Harriet Tucker (harriet.tucker@stgeorges.nhs.uk) 3. Medway NHS Foundation Trust. Investigator name: Adebayo Da-Costa (adebayo.da-costa@nhs.net) 4. Surrey and Sussex Healthcare NHS Trust. Investigator name: Christine Dixon (christine.dixon14@nhs.net) 5. Maidstone and Tunbridge Wells NHS Trust. Investigator name: John Clulow (john.clulow@nhs.net) 6. East Sussex Healthcare NHS Trust. Investigator name: Janet Sinclair (janet.sinclair4@nhs.net) 7. East Kent Hosptials University NHS Foundation Trust. Investigator name: Jonathon Leung (jonathan.leung1@nhs.net) 8. Dartford and Gravesham NHS Trust. Investigator name: Zen Gashi (zen.gashi@nhs.net) 9. King's College University Hosptial NHS Foundation Trust. Investigator name: Matthew Edwards (medwards9@nhs.net) 10. Royal Surrey County Hospital NHS Foundation Trust. Investigator name: Louisa Zouita (l.zouita@nhs.net) **Additional changes to the protocol:** (i) Our project steering committee meeting was held on 11/02/2022 and one of the members commented that the language with regards to call takers and dispatchers was inconsistent. We have made some

				minor changes to the language of the protocol in relevant places to ensure we are being consistent and clear with our explanations. In addition, in the first expert panel meeting one of the members suggested that we should edit the language in the study flowchart on page 13 of the protocol to ensure the language is correct around priority in ambulance dispatching and escalating/de-escalating resources. (ii) The second amendment to the protocol includes an additional paragraph on page 27 to outline additional factors that will be taken into consideration with regards to the progression criteria. In the study steering committee meeting, it was highlighted that the progression criteria should also take into account the acceptability and experience of using live streaming as well as the quantitative data. The research team agreed and have now added a paragraph on page 27 explaining that qualitative findings (e.g. interviews and observations) will also be taken into account when reviewing progression to a subsequent definitive trial. (iii) The third amendment to the protocol includes approval for research nurses at the included trauma units/centres to approach casualties/consultees by telephone/post if they are not able to approach them whilst they are in hospital. In addition, we have added that electronic consent will be acceptable. These points are covered on page 19 of the protocol. We do not believe these changes to the protocol significantly alter the research design, methodology or scientific value of the study.
2	4	18/05/2022	LO/CT	**Addition of 1 NHS organisation** (trauma units/centres) that may need to be included in the study for patient recruitment/data collection. This is not a change to the protocol. 1. University Hospitals Sussex NHS Foundation Trust. Investigator name: Chetan Trivedy (Chetan.trivedy@nhs.net) **Addition of ISRCTN registry number**
5	5	21/07/2022	LO/CT	1. The planned trial period has been changed from February 2022 - July 2022 to June 2022 to November 2022. The study end date has changed to 31st July 2023. We have received a non-cost extension from

				the NIHR to prolong the study end date due to the delayed start. 2a. The inclusion and exclusion criteria have been refined/updated in line with early feasibility testing. 2b. For the London Ambulance Service (LAS) sub-study we have added 'who attempt to use GoodSAM during the call' to our inclusion criteria to ensure it is clear that only calls where GoodSAM is used are eligible for the study. 2c. The randomisation scheme is not possible to be concealed from the research paramedics until the start of the shift as they are supporting EOC staff in preparation for the trial weeks. 3a. The method by which 999 callers are contacted in the main trial. This is not possible to be completed by an emergency operations centre (EOC) administrator so will be completed via EOC staff through the Computer Aided Dispatch (CAD) system. We do not believe this significantly alters the research design or methodology. 3b. The method by which 999 callers are contacted to take part in the survey in the London Ambulance Service sub-study has been updated so that it is clear participants will be phoned to explain the study before receiving a text/email with the survey. This has been updated due to PPIE input/feedback. We do not believe this significantly alters the research design or methodology.
6	6	25/08/2022	LO/CT	1. In the main feasibility study (SECAmb), we have added that telephone (verbal) consent can be taken from patients/consultees for access to the patients medical records, as well as in person, via post and via email. 2a. In the observational sub-study (LAS) we have expanded the study to also include observing the critical care advanced paramedic practitioner (APP) dispatchers (if they consent) when they use GoodSAM for major trauma calls, and include the 999 callers in the invitations to participate in the 999 caller survey.

				2b. We have also changed the start and end date for this observation in the PIS (from May-July to July-Oct). 3a. In the observational sub-study (LAS) we have added that the research paramedic will send a text/email reminder to 999 callers to complete the 999 caller survey up to one week after the incident has occurred. 3b. We have also added that the LAS HEMS or APP dispatcher will ask for permission to share the 999 callers name as well as their phone number with the Research Paramedic so that the research paramedic can personalise their messages/calls to them and track who has completed the 999 caller survey so that reminders are only sent to those that have yet to complete the survey. 4. Updated study documents as per changes 1-3 above. We do not believe that any of these changes are a substantial change or affect the scientific value of the study.

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC committee or MHRA.